

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

IN THE MATTER OF: \_\_\_\_\_ )

) Docket No. TSCA-HQ-2010-5022

Elementis Chromium Inc. )  
f/k/a Elementis Chromium, L.P., )

Respondent. )  
\_\_\_\_\_ )

**INITIAL PRE-HEARING EXCHANGE OF  
RESPONDENT ELEMENTIS CHROMIUM INC.**

Respondent, Elementis Chromium Inc. ("Respondent" or "Elementis Chromium"), respectfully submits this Initial Pre-Hearing Exchange pursuant to Section 22.19(a) of the Rules of Practice, 40 C.F.R. §22.19(a) and the Prehearing Order dated April 28, 2011.

**I. Witnesses to Be Called by Respondent at Hearing**

**A. Fact Witnesses**

Respondent intends to call the following fact witnesses to testify at the hearing in this matter:

**1. Dr. Joel Barnhart**

Dr. Barnhart is Vice President – Technical for Elementis Chromium Inc. ("Elementis Chromium"), a position he has held since 1988. Dr. Barnhart will generally testify as to: Elementis Chromium's membership on the Industrial Health Foundation (the "IHF") Chromium Chemicals Health and Environmental Committee (the "IHF Chromium Committee"); the circumstances behind the IHF Chromium Committee's retention of Applied Epidemiology, Inc. ("Applied Epidemiology") to conduct the

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epidemiology study as reported in the September 27, 2002 "*Collaborative-Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998, Final Report*" (the "September 2002 Four Plant Report"); flaws and limitations associated with the study conducted by Applied Epidemiology for the IHF Chromium Committee; facts regarding communications between Dr. Kenneth Mundt and the IHF Chromium Committee; his analysis and interpretation of the September 2002 Four Plant Report and other versions of that report; that the September 2002 Four Plant Report corroborates, substantially duplicates or confirms well-recognized and well-established serious adverse effects of hexavalent chromium, that EPA had actual knowledge of well-recognized and well-established serious adverse effects of hexavalent chromium; and that he had actual knowledge that EPA had actual knowledge of well-recognized and well-established serious adverse effects of hexavalent chromium.

Respondent reserves the right to have Dr. Barnhart testify in rebuttal to any matter raised by Complainant that is not addressed in Complainant's Initial Prehearing Exchange. To the extent that any of Dr. Barnhart's testimony is considered to be expert in nature, Dr. Barnhart will be offered as an expert witness. Dr. Barnhart's *curriculum vitae* is enclosed herewith as RX 8.

## **2. Dr. Kenneth A. Mundt**

Dr. Mundt is a Principal of ENVIRON International Corporation ("ENVIRON") and was a Principal of Applied Epidemiology until November 1, 2003 when Applied Epidemiology merged into ENVIRON.

Dr. Mundt will testify generally as to: the circumstances behind the IHF Chromium Committee's retention of Applied Epidemiology to conduct the epidemiology study as reported in the September 2002 Four Plant Report; the study conducted by

Applied Epidemiology and reported in the September 2002 Four Plant Report; the findings in the September 2002 Four Plant Report and other versions of that report; flaws and limitations associated with the study conducted by Applied Epidemiology for the IHF Chromium Committee; and public dissemination of the findings from the study conducted by Applied Epidemiology for the IHF Chromium Committee.

Respondent reserves the right to have Dr. Mundt testify in rebuttal to any matter raised by Complainant that is not addressed in Complainant's Initial Prehearing Exchange.

Respondent reserves the right to call additional fact and/or expert witnesses to testify in rebuttal to any matter raised by Complainant that is not addressed in Complainant's Initial Prehearing Exchange.

**B. Expert Witnesses**

Respondent intends to call the following expert witnesses to testify at the hearing in this matter:

**1. Dr. Herman Gibb**

Dr. Gibb is the President of Tetra Tech Sciences, a health and environmental risk assessment consulting organization in Arlington, Virginia. He has a Ph.D. in epidemiology (Johns Hopkins University School of Hygiene and Public Health, 1989) and an M.P.H. in Environmental Health (University of Pittsburgh Graduate School of Public Health, 1974).

Dr. Gibb is expected to testify as to the matters discussed in his affidavit filed in connection with Respondent's Brief in Opposition to Complainant's Motion for Accelerated Decision. Dr. Gibb will testify that the September 2002 Four Plant Report provides no new information with respect to the respiratory risk of hexavalent chromium

and does not add to the knowledge base on the lung cancer risk from occupational exposure to hexavalent chromium. He will further testify that the September 2002 Four Plant Report corroborates, substantially duplicates or confirms well-recognized and well-established serious adverse effects of hexavalent chromium, and that EPA had actual knowledge of well-recognized and well-established serious adverse effects of hexavalent chromium.

Respondent reserves the right to have Dr. Gibb testify in rebuttal to any matter raised by Complainant that is not address in Complainant's Initial Prehearing Exchange.

Dr. Gibb's *curriculum vitae* is enclosed herewith as RX 6.

## **2. Dr. Kenneth Mundt**

Dr. Mundt is a Principal of ENVIRON International Corporation. He has a Ph.D. in Epidemiology from the University of North Carolina at Chapel Hill.

Dr. Mundt is expected to testify as to the matters discussed in his affidavit filed in connection with Respondent's Brief in Opposition to Complainant's Motion for Accelerated Decision. Dr. Gibb will testify that the September 2002 Four Plant Report provides no new information with respect to the respiratory risk of hexavalent chromium and does not add to the knowledge base on the lung cancer risk from occupational exposure to hexavalent chromium. He will further testify that the September 2002 Four Plant Report corroborates, substantially duplicates or confirms well-recognized and well-established serious adverse effects of hexavalent chromium, and that EPA had actual knowledge of well-recognized and well-established serious adverse effects of hexavalent chromium.

Respondent reserves the right to have Dr. Mundt testify in rebuttal to any matter raised by Complainant that is not addressed in Complainant's Initial Prehearing Exchange.

Dr. Mundt's *curriculum vitae* is enclosed herewith as RX 7

## **II. Exhibits Intended to be Introduced into Evidence by Respondent at Hearing**

Respondent intends to introduce the following documents into evidence at the hearing in this matter:

Respondent's Exhibit No.	NAME OF DOCUMENT	No. of Pages
1.	Affidavit of Fredric Arnold, Ph.D. dated April 5, 2011.	7
2.	Affidavit of Glinda Cooper, Ph.D. dated April 5, 2011.	10
3.	Affidavit of Tony Ellis dated April 6, 2011.	2
4.	Affidavit of Oscar Hernandez, Ph. D. dated April 6, 2011.	4
5.	Affidavit of Toni Krasnic dated April 1, 2011	5
6.	<i>Curriculum vitae</i> of Dr. Herman Gibb.	17
7.	<i>Curriculum vitae</i> of Dr. Kenneth Mundt.	18
8.	<i>Curriculum vitae</i> of Dr. Joel Barnhart.	1
9.	September 27, 2002 Final Report "Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958 – 1998"	153
10.	United States Environmental Protection Agency TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33,129-33,140 (June 3, 2003).	12
11.	United States Environmental Protection Agency TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 43 Fed. Reg. 11,110 (March 16, 1978).	7

Respondent's Exhibit No.	NAME OF DOCUMENT	No. of Pages
12.	October 8, 2002 e-mail (excluding enclosures) from K. Mundt to M. Kashek enclosing IHF Chrome Epidemiology Study Final Report (incorporating reviewers' comments) and slides used to present exposure assessment at meeting in Barcelona.	1
13.	Slides used by Dr. Kenneth Mundt to present exposure assessment at meeting in Barcelona in September 2002.	18
14.	April 7, 2003 Final Report "Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958 – 1998"	150
15.	Occupational Safety and Health Administration, Hexavalent chromium, occupational exposure, 71 Fed. Reg. 10100-10385 (February 28, 2006).	287
16.	United States Environmental Protection Agency website, Frequently Asked Questions, TSCA 8(e) Notices, January 14, 2010.	12
17.	Gibb, et al. 2000. Lung Cancer Among Workers in Chromium Chemical Production, American Journal of Industrial Medicine 38:115-126 (2000).	12
18.	Machle W, Gregorius F. 1948. Cancer of the respiratory system in the U.S. chromate-producing industry. Pub. Health Rep. 63: 1114-1127.	14
19.	Baetjer AM. 1950. Pulmonary carcinoma in chromate workers. II. Incidence on basis of hospital records. AMA Arch Indst Hyg and Occup Med 2:505-516.	12
20.	Mancuso TF, Hueper WC, 1951. Occupational cancer and other health hazards in a chromate plant: a medical appraisal. I. Lung cancer in chromate workers. Indust Med and Surg 20:358-363.	6
21.	U.S. Public Health Service. 1951. Health of workers in chromate producing industry—a study. Public Health Service Publication No. 192.	149

Respondent's Exhibit No.	NAME OF DOCUMENT	No. of Pages
22.	Mancuso TF. 1975. Consideration of chromium as an industrial carcinogen. In: Hutchinson TC, editor. Proceedings of the International Conference on Heavy Metals in the Environment. Toronto, Canada: Toronto Institute for Environmental Studies, p 343-356.	14
23.	National Institute of Occupational Safety and Health. 1975. Criteria for a recommended standard.... exposure to chromium (VI). HEW Publication No. (NIOSH) 76-129.	211
24.	Hayes RB, Lilienfeld AM, Snell LM. 1979. Mortality in chromium chemical production workers: a prospective study. Int J. Epidemiol 8(4):365-373.	10
25.	EPA. 1984. Health assessment document for chromium. EPA-600/8-83-14F.	360
26.	IARC. 1987. Monographs on the evaluation of carcinogenic risks to humans. Supplement 7. 1987. International Agency for Research on Cancer, Lyons, France.	449
27.	IARC. 1990. Monographs on the evaluation of carcinogenic risks to humans: chromium, nickel, and welding. Volume 49. International Agency for Research on Cancer, Lyons, France.	687
28.	ATSDR. 1993. Toxicological profile for chromium. Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services.	260
29.	Government of Canada. 1994. Priority substances list assessment report—Chromium and its compounds.	66
30.	Mancuso TF. 1997a. Chromium as an industrial carcinogen: Part I. Am. J Ind Med 31:129-139	11
31.	Mancuso TF. 1997b. Chromium as an industrial carcinogen: Part II. Chromium in human tissues Am J. Ind Med 31:140-147.	8
32.	SMR Analysis of Gibb Study Findings and September 2002 Four Plant Report	1

Respondent's Exhibit No.	NAME OF DOCUMENT	No. of Pages
33.	SMR Analysis of Gibb Study Findings and April 2003 Four Plant Report	1
34.	Analysis of Odds Ratio Findings in September 2002 Four Plant Report	1
35.	K.S. Crump Division. 1995. Evaluation of Epidemiological Data and Risk Assessment for Hexavalent Chromium. Prepared for the Occupational Safety and Health Administration, Washington, D.C. Hexavalent Chromium Docket, Docket H-054A, Exhibit #13-5.	69

Respondent reserves the right to introduce other documents into evidence at the hearing in this matter in rebuttal to any matter raised by Complainant not addressed in Complainant's Initial Prehearing Exchange or for other purposes as allowed by the Federal Rules of Evidence.

**III. Legal and Factual Bases for Respondent's Assertions in Paragraphs 7, 13 and 49 of its Answer**

**A. Assertion in Paragraph 7**

In allegation No. 7 of the Complaint, Complainant alleges that Respondent was the owner and operator of the chromium manufacturing facility located at 5408 Holly Shelter Road, Castle Hayne, North Carolina (the "Castle Hayne Facility") "at all times relevant to this Complaint." Respondent acquired the Castle Hayne Facility in December 2002 from Occidental Chemical Corporation. See Affidavit of Joel Barnhart, Ph.D. attached hereto as Exhibit A. As the relevant times to the Complaint appear to include times before December, 2002, Respondent denied this allegation.

**B. Assertion in Paragraph 13**

In allegation No. 13 of the Complaint, Complainant alleges that Respondent manufactures chromium chemicals from metallic chromium. Respondent does not manufacture chromium chemicals from metallic chromium. See Affidavit of Joel Barnhart attached hereto as Exhibit A. In its Prehearing Exchange, Complainant admits that Respondent does not manufacture chromium chemicals from metallic chromium. Complainant's Prehearing Exchange, at 36.

**C. Assertion in Paragraph 49**

In allegation No. 49 of the Complaint, Complainant alleges that "Respondent did not immediately inform the Administrator of the Final September 2002 Four Plant Report as information which reasonably supports the conclusion that hexavalent chromium exposure present a substantial risk of injury to the health of certain workers in modern chromium production facilities utilizing low-lime or no-lime kiln manufacturing processes, as required by TSCA § 8(e)." Section 8(e) of TSCA does not require that information about substantial risk of injury from a chemical substance be provided to the Administrator if "such person has actual knowledge that the Administrator has been adequately informed of such information." 15 U.S.C. § 2607(e). Complainant's Guidance Policy indicates that any information that corroborates, substantially duplicates or confirms well-recognized and well-established serious adverse effects of a chemical substance does not need to be provided to EPA. See RX 10, p. 11. At the hearing in this matter, Respondent will prove that Complainant has been adequately informed, for more than 25 years, that exposure to hexavalent chromium presents a substantial risk of respiratory cancer at elevated exposure levels, and that Respondent knew that Complainant was adequately informed of such risk. Further, Respondent will prove that the only substantial risk information in the September 2002 Four Plant Report was that an

elevated risk of lung cancer existed in workers who had high cumulative exposures to hexavalent chromium, which finding simply corroborated the well-known and well-established risk. In establishing these facts, Respondent will rely on the documents in Respondent's Exhibit list presented herein, as well as documents introduced by Complainant and testimony from fact and expert witnesses.

Because Respondent had actual knowledge that Complainant was adequately informed of all substantial risk information in the September 2002 Four Plant Report regarding hexavalent chromium, and such information in the September 2002 Four Plant Report simply corroborated, duplicated and confirmed well-known and well-established serious adverse effects already known about hexavalent chromium, TSCA § 8(e) did not require that it be provided to EPA.

**IV. Legal and Factual Bases for Respondent's First, Second, Third and Fifth Affirmative Defenses**

**A. First Affirmative Defense**

*Complainant was adequately informed of the information described in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 at the time of Elementis's alleged receipt thereof.*

The only information on substantial risk of injury from hexavalent chromium contained in the September 2002 Four Plant Report was the finding of a higher incidence of lung cancer for those at the highest exposure level. At the time of Respondent's receipt of the September 2002 Four Plant Report, EPA was in possession of numerous studies that had identified the same substantial risk information. In fact, one such study, performed by Dr. Gibb and others (the "Gibb Study"), was funded by EPA and Dr. Gibb was employed by EPA at the time he conducted the study. Documents in Respondent's

List of Exhibits above, including but not limited to the Gibb Study (RX 17), and testimony from fact and expert witnesses, will be used to support this affirmative defense.

**B. Second Affirmative Defense**

*Elementis had actual knowledge that Complainant was adequately informed of the information described in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 at the time of Elementis's alleged receipt thereof.*

Dr. Barnhart, the Elementis Chromium employee who received the September 2002 Four Plant Report, was well aware of the Gibb Study when he received the September 2002 Four Plant Report, and knew that EPA had funded the study and that Dr. Gibb worked for EPA when he conducted the study. See Affidavit of Joel Barnhart attached to Respondent's Response in Opposition to Complainant's Motion for Accelerated Decision on Liability and documents listed in Respondent's List of Exhibits above.

**C. Third Affirmative Defense**

*At the time of Elementis's alleged receipt of the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998, Complainant was aware of information indicating an increased risk of cancer among certain workers with high levels of exposure in chromium processing plants.*

At the time of Respondent's receipt of the September 2002 Four Plant Report, EPA was in possession of numerous studies that had identified the risk of lung cancer associated with high levels of exposure to hexavalent chromium. As discussed above, the Gibb Study was funded by EPA and Dr. Gibb was employed by EPA at the time he conducted the study. Documents in Respondent's List of Exhibits above, including but

not limited to the Gibb Study (RX 17), and fact and expert witness testimony, will be used to support this affirmative defense.

**D. Fifth Affirmative Defense**

*Complainant's own published guidance and interpretation of law stated that the Toxic Substances Control Act did not require information contained in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 to be disclosed to Complainant.*

EPA published two guidance policies with regard to notification under TSCA § 8(e). The latest of these guidance policies states that any substantial risk information “need not be reported under section 8(e) if it ...[c]orroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose species, strain, sex, time to onset of effect, nature and severity of effect, a well-recognized/well-established serious adverse effect for the chemical(s) under consideration” As explained above, the information in the September 2002 Four Plant Report corroborates, in terms of route of exposure (inhalation), dose (high cumulative exposure) and nature and severity of effect (lung cancer) a well-recognized and well-established effect of hexavalent chromium, namely that high cumulative respiratory exposure to hexavalent chromium results in an increased risk of lung cancer. Thus, pursuant to EPA’s guidance policy, the September 2002 Four Plant Report “need not be reported under section 8(e).” See RX 10 and 11.

**V. Penalty Calculation**

As set forth herein and in other documents filed by Respondent, TSCA § 8(e) did not require that Respondent submit the September 2002 Four Plant Report to EPA. This enforcement action by EPA is therefore without merit and no penalty is appropriate.

Assuming *arguendo* that the Presiding Officer was to determine that Respondent was required by TSCA § 8(e) to submit the September 2002 Four Plant Report to EPA, the penalty calculation provided by Complainant in its Prehearing Exchange is grossly excessive and without merit for the following reasons:

1. The September 2002 Four Plant Report provided no new useful information on risk of injury from hexavalent chromium. In fact, the Occupational Safety and Health Administration expressly so found in the preamble to its rule establishing a new Permissible Exposure Limit for hexavalent chromium in 2006. Two of the top epidemiologists in the world concluded similarly. It would be extraordinary for the Presiding Officer to impose a substantial fine regarding failure to provide a report that a federal agency expressly found (in the context of setting a new PEL), and preeminent epidemiologists determined, provided no new useful information concerning risk of injury from hexavalent chromium.
2. EPA has not promulgated any regulation providing further direction to the regulated community with regard to the one-sentence provision of TSCA § 8(e). The only “guidance” provided by EPA supports the decision made by Respondent that the September 2002 Four Plant Report did not have to be provided to EPA. For EPA to seek a substantial penalty regarding a failure to submit a report that does not fall within either the express language of TSCA or its own guidance, especially given that it has not promulgated any regulation or guidance to guide manufacturers, is fundamentally unfair.
3. Two other very large chromium chemical manufacturing companies, Bayer Corporation and Occidental Chemical Corporation, both received the September

2002 Four Plant Report on the same day that Respondent received the report, yet neither of these sophisticated companies, which were much larger than Respondent, believed that the report was required to be provided to EPA and, in fact, did not provide the report. EPA has not pursued enforcement actions against either of those two companies. EPA's decision to selectively choose to seek a substantial fine on the smallest manufacturer while simultaneously ignoring far larger manufacturers, which had the exact same report and made the same decision concerning whether it should be submitted under TSCA § 8(e), is arbitrary and capricious, and the Presiding Officer should not permit it.

In view of these factors, Respondent's failure to provide it to EPA could only be considered a minor, hyper-technical oversight, rather than the "Major Extent" violation proposed by EPA and its penalty guidance. In setting any penalty, the Presiding Officer should look at this matter for what it is: a very selective and technical enforcement action, stemming from Respondent's reasonable interpretation of the statutory requirement (as well as limited Agency guidance) to an inconsequential but good faith error by a highly experienced and conscientious manufacturer. While Respondent submits no penalty is appropriate because no violation occurred, if a penalty is imposed, it should be nominal and in no case should exceed \$50,000.

#### **VI. Appropriate Place of Hearing**

Respondent's witnesses are located in Alexandria, Virginia, Amherst, Massachusetts and Corpus Christi, Texas. As such, there is not an obviously convenient location for the hearing solely from Respondent's view point. As the majority of Complainant's witnesses are from Washington, DC, and the Presiding Officer is located in Washington, DC as well, Respondent believes that Washington, DC is the most

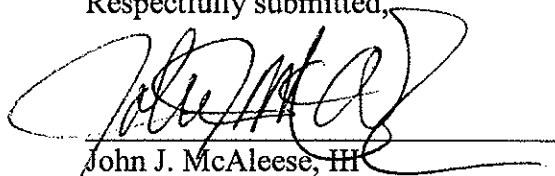
appropriate place for the hearing in this matter. Respondent does not need translation services for any of its expected testimony.

**VII. Estimated Time for Respondent to Present its Direct Case**

Respondent estimates that it will need two days to present its direct case.

Date: June 30, 2011

Respectfully submitted,



John J. McAleese, III  
Ronald J. Tenpas  
William S. Pufko  
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*Attorneys for Respondent Elementis  
Chromium Inc.*

## **EXHIBIT A**

**UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY**

IN THE MATTER OF: \_\_\_\_\_ )

) Docket No. TSCA-HQ-2010-5022

)  
Elementis Chromium Inc. )  
f/k/a Elementis Chromium, L.P., )

)  
Respondent. )  
\_\_\_\_\_ )

**SWORN STATEMENT OF JOEL BARNHART, PH.D.**

I, Joel Barnhart, Ph.D., do hereby state the following:

1. I am currently Vice President – Technical for Elementis Chromium. I have held this position since 1988.
2. Elementis Chromium does not manufacture any chromium chemicals from metallic chromium.
3. Elementis Chromium acquired its manufacturing facility in Castle Hayne, North Carolina in December 2002.

  
\_\_\_\_\_  
JOEL BARNHART, PH.D.

Sworn to and subscribed  
before me this 28 day  
of June, 2011.

  
\_\_\_\_\_  
NOTARY PUBLIC

My commission expires:



**CERTIFICATE OF SERVICE**

I, William S. Pufko, hereby certify that on June 30, 2011, I served a copy of the Initial Pre-Hearing Exchange of Respondent Elementis Chromium Inc. via FedEx on the following:

With Paper Copy and CDs of Exhibits

Ms. Sybil Anderson  
Headquarters Hearing Clerk  
U.S. Environmental Protection Agency  
Office of Administrative Law Judges  
Franklin Court, Suite 350  
1099 14th Street, N.W.  
Washington, DC 20005

Mark A.R. Chalfant, Esquire  
Waste and Chemical Enforcement Division  
Office of Civil Enforcement  
U.S. Environmental Protection Agency  
1595 Wynkoop Street (Mailstop: 8ENF-L)  
Denver, CO 80202-1129

With CD of Exhibits

The Honorable Susan L. Biro  
U.S. Environmental Protection Agency  
Office of Administrative Law Judges  
Franklin Court, Suite 350  
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\_\_\_\_\_  
William S. Pufko